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HAZARD EVALUATION DIVISION

STANDARD EVALUATION PROCEDURE

PESTICIDE SPRAY DRIFT EVALUATION:

DROPLET SIZE SPECTRUM TEST AND DRIFT FIELD EVALUATION TEST

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The Standard Evaluation Procedure for Droplet Size Spectrum Test and Drift Field Evaluation Test, a Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Standard Evaluation Procedure (SEP), prescribes the evaluation criteria and procedures to assess this off-site pesticide transport study that the U.S. Environmental Protection Agency recommends to support the registration of formulated end-use products. This SEP, in conjunction with the Pesticide Assessment Guidelines, Subdivision R, is designed to aid data reviewers in their evaluations of the Droplet Size Spectrum Test and Drift Field Evaluation Test studies submitted by registrants. A summary of the rulemaking off-site transport test requirements can be found in 40 CFR Part 158. The study results contained in the evaluation reports generated in the course of this evaluation procedure together with environmental fate and efficacy data are used to assess the potential hazard of pesticides to nontarget species including humans, plants, fish and wildlife.

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PESTICIDE SPRAY DRIFT EVALUATION:

DROPLET SIZE TEST SPECTRUM AND DRIFT FIELD EVALUATION TEST

I. INTRODUCTION

A. Purpose of the Standard Evaluation Procedure

This Standard Evaluation Procedure is designed to aid Exposure Assessment Branch (EAB) data reviewers in their evaluations of droplet size spectrum and pesticide drift field evaluation studies submitted by registrants in the assessment of pesticide exposure.

B. Background Information

Droplet size spectrum studies and drift field evaluation studies are designed to provide off-site transport data on a pesticide. These off-site transport data are needed to evaluate the effect of pesticide exposure to humans, plants, fish and wildlife by products expected to be applied by aerial, air carrier, mist blower, overhead sprinkler irrigation and other outdoor application equipment. These studies are required by 40 CFR § 158.142 to support the registration of any pesticide intended for outdoor use under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended.

Pesticides with outdoor use patterns where aerial transport of the pesticide to off-site locations is not likely to occur do not have to be evaluated. These use patterns include ground-hydraulic applications. If this or other use patterns do readily expose non-target organisms including humans to the pesticide through aerial transport of droplets, the pesticide drift potential may need to be evaluated.

1. Droplet Size Spectrum Test

The droplet size spectrum studies are performed to determine the influence of a number of equipment and formulation parameters and initial environmental factors on the formation of the droplets as they leave the pesticide dispersal equipment. The major parameters that will be tested are type of nozzle, orientation to the wind shear and formulations. By studying this part of the application process in detail, the more expensive field evaluations will have to be performed less frequently.

2. Drift Field Evaluation Test

The drift field evaluation studies are performed to determine the influence of a number of equipment and formulation parameters and environmental factors on the dispersal of the formulated pesticide from the application equipment to the intended surface(s). The major parameters that will be tested are type(s) of nozzle, orientation to the wind shear, formulations, cross-wind velocity and evaporative factors.

C. Objective of the Pesticide Spray Drift Evaluations

The objective of the pesticide spray drift evaluations is to determine if a pesticide formulation applied as directed has the potential to be transported to off-site, non-target areas and thereby cause detrimental effects on non-target plants, animals and humans. The extent of possible detrimental effects on plants, animals and humans will be determined by various scientists evaluating phytotoxicity, fish, wildlife and insect toxicity, and human and domestic animal toxicity. These tests are required by 40 CFR § 158 and the Pesticide Assessment Guidelines, Subdivisions E, F, J and L: Hazard Evaluation.

1. Droplet Size Spectrum Test

The droplet size spectrum test provides information on the effects of pesticide application equipment and formulations on droplet sizes which in turn influence the extent of pesticide droplets being carried by air currents to non-target areas. Quantification of the pesticide movement by air currents is evaluated in the succeeding study on pesticide drift field evaluation.

2. Drift Field Evaluation Test

The drift field evaluation test provides information on the effects of the environment and application equipment on the extent of off-site, off-target transport of pesticides by air currents immediately following release from application equipment. The extent and quantity of drift will be determined in order that it can be compared to toxicological study information for possible effects on non-target plants, wildlife and humans. It is important to note that it is not the purpose of the drift field evaluation study to evaluate the extent of aerial movement of a pesticide as a result of evaporation of the material from plant, soil or other substrate surfaces after deposition.

II. INFORMATION TO BE SUPPLIED

The registrant's reports on droplet size spectrum and drift field evaluation studies should include all information necessary to provide: 1) a complete and accurate description of the treatments and procedures, 2) sampling data, 3) data on storage of the samples until analysis, if so performed, 4) any chemical analysis of the collection surfaces as to chemical content, if so performed, 5) recovery efficiency, 6) reporting of the data, rating system and statistical analysis, and 7) quality control measures/precautions taken to ensure the fidelity of the operations.

A guideline of specific information that should be included in the registrant's report on droplet size spectrum and drift field evaluation studies is provided in Appendix 1 of this document.

This list of requested information and reviewer aids is derived from the Pesticide Assessment Guidelines, Subdivision R: Pesticide Spray Drift Evaluation, which is complemented by this Standard Evaluation Procedure.

III. DATA INTERPRETATION

The acceptability of the study results will depend upon whether the test requirements/standards are followed. If a deviation is made, a determination must be made as to whether the deviation has changed the quality of the results in such a manner that the results cannot be extrapolated to the natural environment. There should be little or no deviation from the liberalized standards prescribed in this study.

The results of the droplet spectrum study for the chemical formulation with respect to the quantity of pesticide applied and nozzles used are important. The concentration of the chemical in the carrier is important in that varying concentrations can lead to large variations in droplet size spectrums. The results of the drift field evaluation study for the chemical formulation with respect to the quantity of pesticide applied and nozzles used are also important. This will help quantify the pesticide off-target movement due to equipment and environmental conditions and enable the Agency to prepare exposure assessments for the chemcial and that use pattern.

There is no decision point for the droplet size spectrum with respect to performing the drift field evaluation study. There is also no decision point for the drift field evaluation study with respect to performing additional studies.

IV. THE DATA EVALUATION PROCESS

Upon careful examination of the information/data supplied by the registrant in his submission to the Agency, the reviewer shall evaluate the data as follows.

A. Identify Data Gaps

Using Appendix 1 of this document as a guide, the reviewer should look for data gaps - omissions in the information supplied by the registrant in his report. These should be duly noted in the reviewer's report and a judgment made as to which are considered significant enough to adversely affect the review process. Those so identified should be communicated back to the registrant by the Product Manager for corrective action.

B. Assess the Appropriateness and Adequacy of the Data

The data reviewer then considers the appropriateness, i.e., the intended use pattern, and adequacy of the data/information that has been supplied. Appendix 1 of this document is a useful guide to the various parameters that need to be considered. Appendix 2 provides specific questions that should be answered by the reviewer during the study evaluation process. Statistical treatments of the data should be independently verified and the quality control precautions noted.

As an adjunct to these, the reviewer should draw upon the technical guidance in the reviewer aids materials that are available. (See also the recommmended references in Subdivision R - Pesticide Spray Drift Evaluation.) A listing of additional source materials is located in the References section of this document.

In addition to the data gaps noted above, any perceived deficiencies in the data/information supplied should also be identified. A statement as to these deficiencies should be made in the reviewer's report and corrective action to resolve them should be provided. This information can be relayed to the registrant by the Product Manager for appropriate action.

C. Report Preparation

The Agency reviewer prepares a standard review report following the standard format for preparation of scientific reviews as provided in Appendix 3 of this document. All important information provided by the registrant including the methodology and results is to be summarized in order that future evaluations can be made. The results may be expressed in the form of tables where specific values are related. Figures (graphs) may be provided but are not to be the sole source of the values needed for future evaluations.

D. Conclude if the Requested Action is Supportable

Lastly, the reviewer considers the results of the droplet size spectrum/drift field evaluation studies and makes a judgment as to whether they support the requested registration action of the data submitter. If the data are not supportive, possible alternative action(s) that may be taken by the registrant, such as label modifications, are suggested. If deficiencies/omissions exist in the submitted data, the reviewer may have to defer judgment until such time as appropriate corrective action has been rendered by the registrant.

APPENDIX 1

INFORMATION REQUESTED OF THE REGISTRANT

The registrant's report on droplet size spectrum and drift field evaluation studies should include all information necessary to provide: 1) a complete and accurate description of the treatments and procedures, 2) sampling data, 3) data on storage of the samples until analysis, if so performed, 4) any chemical analysis of the collection surfaces as to chemical content, if so performed, 5) recovery efficiency, 6) reporting of the data, rating system and statistical analysis, and 7) quality control measures/precautions taken to ensure the fidelity of the operations.

Specifically, each report should include the following information.

I. General

° Cooperator or researcher (name and address), test location (county and state; country, if outside of the U.S.A.), and date of study;

° Name (and signature), title, organization, address and telephone number of the person(s) responsible for planning/supervising/monitoring;

° Trial identification number;

° Quality assurance indicating: control measures/precautions followed to ensure the fidelity of the droplet size and/or drift field determinations; record-keeping procedures and availability of logbooks; skill of the laboratory personnel; equipment status of the laboratory; degree of adherence to good laboratory practices; and degree of adherence to good agricultural practices for application of pesticides; and

° Other information the registrant considers appropriate and relevant to provide a complete and thorough description of the test procedures and results.

II. Test Substance (Pesticide)

° Identification of the test pesticide active ingredient (ai) including chemical name, common name (ANSI, BSI, ISO, WSSA), and Company developmental/experimental name;

° Active ingredient percentage by weight in the formulated end-use product used or substituted (with reasons for substitution of end-use product);

° Type of formulation (e.g., emulsifiable concentrate, flowable powder, liquid, etc.);

° Dose rate(s) in terms of active ingredient per unit area of land or in gallons-per-minute (gpm) (liters-per-minute [lpm]); and

A. Droplet Size Spectrum Tests

° Method of droplet testing (wind tunnel, aircraft, mist blower).

B. Drift Field Evaluation Tests

° Identification of the use of dyes or other indicators; and

° Identification of adjuvants used and other tank mixed pesticides.

III. Collection Surfaces

A. Droplet Size Spectrum Tests

° Identification of the collection surfaces. The collection surfaces may include laser particle measuring systems (PMS), collection cards (flat horizontal or vertical surfaces), air samplers or other devices by which droplet size distribution can be measured;

° Identification of the number of replicates; and

° Distance between nozzles and collection surface/detection device.

B. Drift Field Evaluation Tests

° Identification of the collection surfaces. The collection surfaces may include collection cards (flat horizontal or vertical surfaces), air samplers or other devices by which droplet size distribution can be measured, as necessary, and the down-wind pesticide movement can be quantified;

° Identification of the number of replicates; and

° Identification of the placement of the collection surfaces with respect to the vegetation canopy or other anticipated surface(s), treated area and wind direction.

IV. Site of the Test

A. Droplet Size Spectrum Tests

° Type of site of the droplet size spectrum study as to whether the study was performed in or out of a wind tunnel or in the field during the drift field evaluation study; and

° Climatological data (records of applicable conditions for the type of site, i.e., temperature, air flow or velocity, wind direction [field study], relative humidity).

B. Drift Field Evaluation Tests

° Location of the test site;

° Site description of the drift field evalaution such as type of forest, field or grove, etc.;

° Climatological data (records of applicable conditions for the type of site, i.e., temperature, thermoperiod, rainfall or watering regime, photoperiod, air velocity and wind direction, relative humidity); and

° Field lay-out (graphic display is encouraged).

V. Application Equipment

° Nozzle type, orifice size, and core identification;

° Nozzle pressure, flow rate and orientation to the airstream; and

° For drift field evaluation tests, identification of the typical and actual equipment(s) for the application of the pesticide under the use patterns that are being evaluated.

VI. Results

A. Droplet Size Spectrum Tests

° The particle size distribution versus cumulative percent volume and versus droplet number (frequency); and

B. Drift Field Evaluation Tests

° The quantity of active ingredient(s) or acid equivalent collected or detected at each sampling point in terms of kilograms per hectare (or pounds per acre).

VII. Evaluation

A. Droplet Size Spectrum Tests

° The 10th, 50th and 90th percentile of the size distributions with respect to droplet volume and number and standard deviations, where possible.

B. Drift Field Evaluation Tests

° The overall movement of the pesticide formulation as a result of aerial transport.

APPENDIX 2

SPECIFIC QUESTIONS FOR THE REVIEWER

The following questions are provided to aid the reviewer in performing the standard evaluation procedure in a scientific manner and to complete a scientific review.

I. General

- Were the name of the cooperator or researcher (name and address), test location (county and state; country, if outside of the U.S.A.), and date of study provided?

- Were the name (and signature), title, organization, address, and telephone number of the person(s) responsible for planning/supervising/monitoring and, for small field plot studies, applying the pesticide provided?

- Was the trial identification number provided?

- Were quality assurance control measures/precautions indicated?

II. Test Chemical

- Was the test chemical being used the proposed formulated end-use product or of the same formulation category as the end-use product to be registered?

- Was the active ingredient percentage or degree of purity of the chemical given?

- Was the application rate given in quantity per unit area (of plant or land surface) or in quantity per minute (gallons-per-minute or liters-per-minute)?

- Was the application rate the maximum label-recommended rate?

- Were the physical properties of the total formulation given including surface tension, viscosity, density and vapor pressure?

A. Droplet Size Spectrum Tests

- Were diluents and extent of dilution identified along with possible adjuvants, tank mixtures with other pesticides?

B. Drift Field Evaluation Tests

- Were diluents or carriers, and the extent of dilution identified along with possible adjuvants, tank mixtures with other pesticides, and total spray volume?

° Were tank mixes evaluated, if so specified, for the intended use pattern that was being evaluated?

° Were controls used to note any possible decay or other loss of pesticide during the collection, transport, storage and analysis?

III. Collection Surfaces

A. Droplet Size Spectrum Tests

° Were the collection surfaces or devices identified along with the equipment limitations? Equipment limitations include the resolution of the microscopes, particle measuring systems, or air samplers, and the spread factor of the droplets on the various collection surfaces (cards).

° Were at least three replicates of each test produced or were multiple samples taken from only one replicate, i.e., were several different sets of nozzles of the same type tested?

B. Drift Field Evaluation Tests

° Were at least two replicates of each sample position produced or were multiple samples taken from only one replicate?

° Were the distribution of the collection surfaces of sufficient number to establish a definitive uninterrupted picture of deposits across the treated swath as well as outside the target area?

° Did the collection pattern extend 1000 feet downwind for aerial and air carrier applications and 500 feet for other ground applications?

° Were the collection surfaces placed at the soil surface or at the height of the surrounding canopy?

° Were air samplers employed, and if so, were they at least three downwind locations (one preferrably at the farthest downwind site)?

IV. Test Procedures

A. Droplet Size Spectrum Tests

° Was the test site specified, i.e., wind tunnel, or field evaluation?

° Were the environmental conditions that prevailed during the test (temperature, relative humidity, air velocity) provided?

° Were the environmental conditions, especially wind velocity, steady throughout the evaluation?

B. Drift Field Evaluation Tests

° Was the test site specified, i.e., open field, cropped field, forest, grove, etc.?

° Were the environmental conditions that prevailed during the test (temperature at two levels, relative humidity, air velocity and direction, rainfall or watering regime [overhead irrigation systems]) provided?

° Were the environmental conditions that prevailed during at least one field test those conducive to the extensive drift of the pesticides?

° Were the environmental conditions, especially wind velocity, steady throughout the evaluation?

V. Application Equipment

° Were the nozzles those most likely to be used for the application of that pesticide or the intended use pattern?

° Were the nozzle pressure, flow rate and orientation to the airstream given?

A. Droplet Size Spectrum Tests

° Were the nozzles tested the same as those most likely to be used in the application of that pesticide?

B. Drift Field Evaluation Tests

° Was at least one test run performed with nozzles and other equipment configurations that would result in conditions conducive to the extensive drift of the pesticides?

° Was the speed of the equipment over the ground given?

° Was the estimated minimum and maximum nozzle-to-target height provided?

VI. Reporting

A. Droplet Size Spectrum Tests

° Were the particle size distribution versus cumulative percent volume and versus droplet number (frequency) given?

B. Drift Field Evaluation Tests

° Were the particle size distribution versus cumulative percent volume given and versus droplet number (frequency) given if the droplet size spectrum study was performed as part of the field evaluation?

° Was a diagram of the plot or area provided indicating north, swath width, and orientation, prevailing wind direction, and location of the collection stations?

° Was the Barad stability ratio calculated?

° Were the quantities of pesticide at each collection station and quantity of pesticide per area (g/ha) given?

VII. Evaluation

A. Droplet Size Spectrum Tests

° Were the results tabulated to indicate a 10th, 50th and 90th percentile of particle size distribution with respect to droplet volume and number?

B. Drift Field Evaluation Tests

° Was the extent of downwind spray drift evaluated with respect to possible exposure to the non-target organism(s) that may be detrimentally affected?

APPENDIX 3

SAMPLE STANDARD FORMAT FOR PREPARATION OF SCIENTIFIC REVIEWS

The following format shall be used in documenting the review of the Subdivision R: Pesticide Spray Drift Evaluation - Droplet Size Spectrum and Drift Field Evaluation Studies.

Chemical: (Common Name)

Formulation: (Percent Active Ingredient and Formulation Type)

Study/Action: (Purpose of the Submission)

Study Identification:

(Subdivision R Test Title)
(Reference or Registrant Data Information with Study Number)
(EPA Accession Number)

Reviewer: (Name and Address of Reviewer; Date of Review)

Approval: (Quality Control Reviewer)

Conclusions: (Summary and Conclusion of Tests)

Acceptability and Recommendations:

(Decide as to (1) the scientific validity of the study, (2) compliance to the Subdivision R - Droplet Size Spectrum Test or Drift Field Evaluation Test guideline, (3) data gaps, and (4) additional information required by Agency.)

Background: (Introductory Information and Directions for Use)

Discussion:
1. Study Identification
2. Materials and Methods
3. Reported Results
4. Reported Conclusions
5. Reviewer's Interpretation of Results and Conclusion

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